



FeF Benzalkonium Chloride

Ph.Eur., USP/NF, JP

Application

FeF Benzalkonium Chloride Ph.Eur., USP/NF, JP (BKC Multicompendial) is a viscous liquid made of quaternary ammonium compounds. FeF BKC Multicompendial is a very efficient germicide which is active against most common micro-organisms, such as bacteria, fungi and algae. FeF BKC Multicompendial is widely used in pharmaceuticals as the active ingredient (API) due to its anti-microbial effect and as an excipient because of its preserving properties.

Item No. 7800012 (1 kg)

Item No. 7800013 (5 kg)

Specifications

Identification:	Complies to Ph.Eur., USP/NF, JP
Appearance of solution:	Max. as ref. susp. I Max. as ref. solution Y6.
Purity 1:	Clear and colourless to light yellow
Purity 2:	Max. 1.0 % w/w
Acidity or alkalinity:	Max. 0.1 ml 0.1M HCl or NaOH
Ratio of alkyl components:	C12: 60 - 70%w/w, C14: 30 - 40%w/w, C16: Max. 5%w/w
Benzyl alcohol (A):	Max. 0.5% w/w
Benzaldehyde (B):	Max. 0.15% w/w
(Chloromethyl)benzene (C):	Max. 0.05% w/w
Any other detectable impurity:	Max. 0.10% w/w
Amines and amine salts:	Max. 1.0 ml/g
Water:	Max.10.0% w/w
Sulphated ash (Ph.Eur.) / Residue on ignition (USP/NF, JP):	Max. 0.1% w/w
Water-insoluble matter:	No turbidity and insoluble matter
Assay (anhydrous basis):	Ph.Eur.: 95.0 - 104.0% w/w USP/NF: 97.0 - 103.0% w/w JP: 95.0 – 105.0% w/w
Total Aerobic Microbial Count:	Max. 1 CFU/g
Total comb. Yeast/Mould Count:	Max. 1 CFU/g
Staphylococcus aureus:	Absent in 1 g
Pseudomonas aeruginosa:	Absent in 1 g
Salmonella spp.:	Absent in 10 g
Escherichia coli:	Absent in 1 g
Bile-tol. gram-neg. bact.:	Absent in 1 g

Description

Composition:	FeF BKC Multicompendial consists of Benzyl (dodecyl) dimethyl ammonium chloride (approx. 65%) and Benzyl (tetradecyl) dimethyl ammonium chloride (approx. 35%). FeF BKC Multicompendial contains approx. 95% active ingredients.
CAS No.:	8001-54-5
EINECS No.:	264-151-6
Names:	Benzalkonium Chloride (BKC). Alkyl dimethyl benzyl ammonium chloride.
Appearance of product:	Clear, or white to yellowish-white solid or viscous liquid. May contain yellowish-white fragments.
Chain length:	60-70% w/w C ₁₂ , 30-40% w/w C ₁₄ and Max. 5% w/w C ₁₆ .

Technical information

Standards:	The quality system meets DS/EN ISO 9001. The environmental system meets DS/EN ISO 14001.
Grade:	Pharmaceutical grade.
Quality:	The product is manufactured in accordance with the cGMP Guide for Active Pharmaceutical Ingredients (API) ICH Q7.
Documentation:	Certificate of Suitability (CEP)
TSE:	FeF BKC Multicompendial does not contain materials of animal origin.
Solubility:	FeF BKC Multicompendial is miscible with water or lower alcohols, such as methanol, ethanol and propanol in all ratios. FeF BKC Multicompendial is neither miscible with benzene nor ether.
Compatibility:	Mixing FeF BKC Multicompendial with ordinary soaps and/or with anionic detergents may decrease the activity.
Density:	Approx. 0.98 g/ml.
Packaging:	FeF BKC Multicompendial 1 kg is packaged in rectangular HDPE plastic containers with tamper proof LDPE Caps. FeF BKC Multicompendial 5 kg is packaged in round PP plastic containers with tamper proof PP lids.
Shelf life:	5 years.
Storage:	Store at temperatures above 15°C. Store protected from excessive heat. FeF BKC Multicompendial may be a liquid, paste or solid depending on the storage conditions.

Safety and handling

See the Material Safety Data Sheet on novonordiskpharmatech.com

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